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# TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER 200.1163US

INTERNATIONAL APPLICATION NO.
PCT/US2004/029521

INTERNATIONAL FILING DATE

09 September 2004

U.S. APPLICATION NO. (CONOUTS BE A 25.R41.5) 4
PRIORITY DATE CLAIMED

September 25, 2003

TITLE OF INVENTION

PHARMACEUTICAL COMBINATIONS OF HYDROCODONE AND NALTREXONE

APPLICANT(S) FOR DO/EO/US Benjamin Oshlack et al. Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. The US has been elected (Article 31). A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (required only if not communicated by the International Bureau). has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). 6. An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). 7. Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. A have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: 11. An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. A preliminary amendment. 14. An Application Datasheet under 37 CFR 1.76. A substitute specification. 16. A power of attorney and/or change of address letter. 17. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825. 18. A second copy of the published international application under 35 U.S.C. 154(d)(4). 19. A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mall Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Other items or information: Unexecuted Declaration/Power of Attorney; Express Mail Label EV 717 227 572US

## IAP15 Rec'd PCT/PTO 28 DEC 2005

PTO-1390 (Rev. 2-2005)
Approved for use through 3/31/2007. OMB 0651-0021
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U.S. APPL	ICATI	A NZ	known s	#49°4	50)			PPLICATION 14/029521	NO.			YS DOCKET NO. 1.1163US	
				ve been subm						CAL	CULATIONS	PTO USE ONLY	
21. 🛛	-	Basic na	tional fee				•••••	\$300		\$ 30	0.00		
22.		Examina	tion fee										
If International preliminary examination report prepared by USPTO ands all claims satisfy										\$ 20	0.00		
provisions of PCT Article 333(1)-(4) \$100 All other situations \$200										<b>\$20</b>	0.00		
23. 🔀	23. Search fee Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the												
USPTO as an International Searching Authority\$100										\$ 40	0.00		
International Search Report prepared and provided to the Office\$400 All other situations\$500													
TOTAL OF 21, 22 and 23 =										\$ 90	0.00		
Additional fee for specification and drawings filed in paper over 100 sheets (excluding													
sequence listing or computer program listing filed in an electronic medium).  The fee is \$250 for each additional 50 sheets of paper or fraction thereof.													
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Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e))+										\$			
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Applicant claims small entity status. See 37 C.F.R. 1.27. Fees above are reduced by 1/2.										\$			
SUBTOTAL =										\$			
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).										\$			
TOTAL NATIONAL FEE =										\$ 12	00.00		
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be													
	accompanied by an appropriate cover sheet (37 CFR 1.21(n)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +										\$		
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a. A check in the amount of \$1200.00 to cover the above fees is enclosed.													
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c. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0552. A duplicate copy of this sheet is enclosed.													
d. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information													
should not be included on this form. Provide credit card information and authorization on PTO-2038.  NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or													
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Davidson, Davidson & Kappel, LLC  485 Seventh Avenue, 14th Floor													
New York, NY 10018 Robert J. Paradiso													
(212)-736-	(212)-736-1940 NAME												
Dated: D	Dated: December 28, 2005  A1,240 REGISTRATION NUMBER												

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#### Certificate of Express Mailing under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 in an envelope addressed to:

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Re.: Docket No.: 200.1163US

Applicant(s): Benjamin OSHLACK Serial No.: To be Assigned

Invention: Pharmaceutical Combinations of Hydrocodone and Naltrexone

Filing Date: Herewith

#### **Enclosed Are:**

- Transmittal Letter (35 U.S.C. 371) (2 pages);
- Application Data Sheet (2 pages);
- Preliminary Amendment (7 pages);
- Unexecuted Declaration/Power of Attorney Form (2 pages);
- Letter re priority (1 page);
- Copy of published International Appl. No. PCT/US2004/029521 (76 pages);
- Return Postcard; and
- Check in the amount of \$ 1200.00

This collection of information is required by 37 CFR 1.10. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.8 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.